MANUFACTURER'S DECLARATION OF CONFORMITY- DoC - OtoNova United Kingdom- UK [UK DoC- OtoNova]

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity (according to EN ISO/IEC 17050-1:2010 and UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

Manufacturer's name:	**OTODYNAMICS LTD**
Business address:	30-38 Beaconsfield Rd Hatfield, Hertfordshire AL10 8BB, UK
Responsibility Statement:	This UK declaration of conformity is issued under the sole responsibility of Otodynamics Ltd. Otodynamics Ltd declares that the OtoNova product (s) covered in this document are in conformance with the requirements of UK MDR 2002 (SI 2002 No 618, as amended).
Medical device(s):	**OtoNova** Otoacoustic Emission- **OAE** and Auditory Brainstem Response- **ABR** Analyser System for Use in the Analysis and Diagnosis of Hearing Loss with Nova- Link Software for Screening, Diagnosis and Data Management.
Classification:	**Class IIa** under rule 10 of Annex IX of Directive 93/42.
GMDN code and term:	(35747) _Evoked-potential audiometer; (58019) _Otoacoustic emission system, battery-powered.
UMDNS Code and term:	(17601) _ Auditory Function Screening Devices; (16303) _ Audiometric Evoked-Potential Units.
European Medical Device Nomenclature (EMDN):	Z12149001)_Otoacoustic Emissions Equipment; (Z12140302)_ Evoked Potential Audiometry Equipment

Scope of application

Current **OtoNova** medical device with Nova-Link software (S/W) Screening & Clinical application variants:

Variant Names	Variant Code (REF)	UDI-DI (GTIN-14)	Basic UDI-DI
OtoNova Screener	NOVA-SCR-TE	05060396171543	506039617OTONOVAUA
	NOVA-SCR-DP	05060396171550	
	NOVA-SCR-ABR	05060396171567	
	NOVA-SCR-DPTE	05060396171574	
	NOVA-SCR-TE+ABR	05060396171581	
	NOVA-SCR-DP+ABR	05060396171598	
	NOVA-SCR-DPTE+ABR	05060396171604	
OtoNova Clinical	NOVA-CLN-DPTE +ABR	05060396171628	

OtoNova with Nova-Link software are capable of performing three complementary hearing test types: Transient Evoked Oto-Acoustic Emissions (TE); Distortion Product Oto-Acoustic Emissions (DP); and Auditory Brainstem Response (ABR). *The OtoNova variant code describes the specific configuration of these Test Types the customer has selected, controlled by a software license. Further information ref. INF191-91-1.* OtoNova Pro variants have binaural capability and an enhanced electrodes connection. OtoNova Pro is part of OtoNova family of products.

UK CA 0120

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Current Good Manufacturing Practices- cGMP Statement

The Otodynamics UK facility, located in Hatfield, Hertfordshire, manufactures a range of OAE & ABR medical devices that are globally distributed to healthcare industry. Products manufactured at our Otodynamics UK facility are produced using applicable medical devices cGMP based on EN ISO 13485: 2016+A11:2021, FDA 21CFR820 and regulations. Otodynamics operates under a state of continuous quality control per regulations and the Quality Management System- QMS reflects activities associated with product design, manufacture, sales, distribution and service.

- MHRA- Medicines and Healthcare products Regulatory Agency is the Competent Authority- CA in the UK.
- The UK Approved Body SGS UK Ltd (AB 0120) carries out the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) conformity assessment procedures on the medical devices.
- SGS UK Ltd carries out the QMS EN ISO 13485 conformity assessment procedures on the company.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:

Otodynamics UK CA Certificate Full Quality Assurance System: SGS Certificate GB24/00000028

United Kingdom Conformity assessment certificate under procedures performed based on Part II of United Kingdom- UK Medical Devices Regulations- MDR 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to the UK MDR 2002]. (Audit of Full Quality Assurance- QMS/ Technical Documentation).

The Certificate is valid from 01 February 2024 until 01 February 2029. Issue 1. Certified since 01 February 2024.

Approved Body: SGS United Kingdom Ltd, AB0120, Rossmore Business Park Ellesmere Port, Cheshire, CH65 3EN, UK.

QMS: EN ISO 13485:2016 & EN ISO 14971:2019. SGS Certificate: GB97/10852, Valid from 01 February 2024 until 01 February 2027. Issue 20. Certified since 12 September 1997.

SGS United Kingdom Ltd, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK.

Declarations/ regulations applied:

The **OtoNova** and Nova-Link Software declared to be in compliance with current UK MDR 2002 on medical devices as amended (taking account of the intended purpose of the devices concerned as they are covered by the UK MDR).

- We confirm that the **OtoNova** medical devices we supply UK are compliant with the applicable requirements of UK MDR 2002.

In addition, these **OtoNova** products comply with the requirements of REACH Regulation EC) No 440/2008 & (EC) No 1907/2006; of the WEEE Directive 2012/19/EU; of the RoHS Directive 2011/65/EU (RoHS 2) and "Packaging Directive" 94/62/EC.

Declared Conformance to the following standards:

Safety: EN 60601-1:2006+A2:2021 (IEC 60601-1, ed. 3.2); EN 60601-1-6:2010+A2:2021 (IEC 60601-1-6, ed. 3.2); EN 62366-1:2015+A1:2020 (IEC 62366-1, ed.1.1); EN 60601-2-40:2019 (IEC 60601-2-40:2016); EN 62304: 2006+ A1:2015; PD ISO/ TR 80002-2: 2017.

EMC: EN 60601-1-2:2015 +A1:2021 (IEC 60601-1-2, ed. 4.1).

Other: EN/IEC 60645-1:2017; EN/IEC 60645-3:2020; EN/IEC 60645-6:2022; EN 60645-7:2010, IEC (2009); EN ISO 10993-1:2020; EN IEC 63000:2018; EN 50419:2022; EN ISO/IEC 17050-1:2010; EN ISO 20417:2021; EN ISO 15223-1:2021; EN ISO 14155: 2020; EN 60601-1-9:2008+A2:2020; EN ISO 14001:2015; EN ISO 14040:2006+A1:2020; EN ISO/IEC 27001:2022; EN ISO 27799:2016; ISO/IEC 27032:2012; EN 62353:2014; ISTA Procedure 3A (18-18); ASTM D4332 – 14.

Declarations/Conformity:

OtoNova products do not contain any of the restricted substances in concentrations and applications not permitted by the RoHS Directive (maximum concentration values tolerated by weight in homogeneous Materials):

- Cadmium (Cd- 0.01 %); Lead (Pb – 0.1 %); Hexavalent Chromium (Cr6+- 0.1 %); Mercury (Hg- 0.1 %); PBB's (Polybrominated biphenyls) (PBB- 0.1 %); PBDE's (Polybrominated diphenyl ethers) (PBDE 0.1 %);
- Adaptation of RoHS Directive issued (2015/863/EU) for the four additional phthalate substances: Bis (2-ethylhexyl) phthalate (DEHP – 0.1%); Butyl benzyl phthalate (BBP – 0.1%); Dibutyl phthalate (DBP – 0.1%); Diisobutyl phthalate (DIBP – 0.1%).
- Otodynamics **OtoNova** products do not contain phthalates.

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Registered in England • Company No: 2289571 • VAT No: GB 539 9876 66 • FDA Region: 8021990 • Producer Reg No: WEE/BF035QU

- No Ozone Depleting Substances are used by Otodynamics/ its Products.
- None of the following are used by Otodynamics/ its Products: Polychlorinated Biphenyls (PCBs); Chlorinated Paraffins; brominated flame retardants, asbestos, chlorofluorocarbons (CFC's), hydrochlorofluorocarbons (HCFC's), hydrofluorocarbons (HFC's), Tributyl Tin (TBT); Triphenyl Tin (TPT) and Tributyl Tin Oxide (TBTO).
- Otodynamics products do not contain Materials Derived from Animal Sources. Otodynamics products are not made with Natural Rubber Latex.
- Materials used in the manufacturing processes for the Otodynamics products are Not Substances of Very High Concern (SVHC) and are in line with REACH regulations.

OtoNova product packaging is reusable. The **OtoNova** medical device/ system is not supplied sterile or intended to be sterilized by the user. It is recommended that probe Ear Tips, Electrodes and Ear Cups are for single PATIENT use only.

OtoNova System Items:

The Ear probes and the below items are part of the OtoNova device system- together they are a class IIa medical device. UPS, UPD & XPD Ear Probes/ Spares (Body/ Lid & Coupler Tubes, Tip Holders, Filters), Probe Ear Tips; Probe Pouch; Probe Cable Clip; Test Cavity; Charger Power Supply; Wireless Charger; Electrode Cables/ Electrodes; Ear Cups; ABR Starter Kit; Otolink Software; Calibration Unit; Device Hook, Crib/Bassinette; Carry Case; **OTONOVA** ABR BINAURAL; **OTONOVA** Tablet. More details are provided in the product manual. Reference the "F-008-58 OtoNova Technical, Clinical Description & Declaration – DoC attachment Rev001" attachment document to this UK DoC for the complete list of OtoNova items.

Authorised signatory: person responsible for regulatory compliance. **Place of Issue:** Otodynamics Ltd, Hatfield, Herts, UK.

Anastasios Parasiris	Product Quality Assurance & Regulatory Assurance Manager	Anastasios Parasiris	01/02/2024
Name	*Position*	*Signature*	*(DD/MM/YYYY)*

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